

### **Remarks**

Claim 4 has been amended and claims 1-48 are pending for reconsideration, which is respectfully requested in view of the foregoing amendments and following remarks.

In the Office Action mailed December 15, 2003, the Examiner alleged that claim 4 was indefinite under 35 USC § 112, second paragraph. Claims 1, 3-5, 9, 11, 12, 16, 19-22, 26, 39-41, 43, and 46 were rejected under 35 USC § 102(e) over US Patent No. 5,776,456. Claims 1-12, 14-27, 32, 37-39 and 41-48 were rejected under the doctrine of obviousness-type double patenting over claims 1-5, 7-22, 25, 32, and 33 of US Patent No. 6,306,393. Claims 1-12, 14-27 and 32-48 were rejected under the doctrine of obviousness-type double patenting over claims 1-5, 7-22, 25, 32, and 33 of US Patent No. 6,306,393, in view of US Patent No. 5,837,242. Claims 1-12, 14-28, 32, 37-39 and 41-48 were rejected under the doctrine of obviousness-type double patenting over claims 1-5, 7-22, 25, 32, and 33 of US Patent No. 6,306,393, in view of Rybak. Claims 1-12, 14-27, 32, 37-39 and 41-48 were rejected under the doctrine of obviousness-type double patenting over claims 1, 4-13, 15-19, and 23 of US Patent No. 6,183,744. Claims 1-12, 14-27, and 32-48 were rejected under the doctrine of obviousness-type double patenting over claims 1, 4-13, 15-19, and 23 of US Patent No. 6,183,744, in view of US Patent No. 5,837,242. Claims 1-12, 14-28, 32, 37-39 and 41-48 were rejected under the doctrine of obviousness-type double patenting over claims 1-5, 7-22, 25, 32 and 33 of US Patent No. 6,183,744, in view of Rybak. The specific grounds for objection, and applicants' response thereto, are set out in detail below.

### **Priority claim**

The Examiner states that priority to US applications 09/038,955 and 09/307,816 has been denied because these applications allegedly fail "to provide support under 35 USC § 112 for all the claims of the application." (emphasis supplied). Applicants note that priority must be determined on a claim by claim basis and that therefore the Examiner's blanket denial of priority for all claims is improper and should be withdrawn. See generally MPEP 201.11.

**Rejection under § 112, second paragraph**

The Examiner alleges that claim 4 is indefinite under 35 USC § 112, second paragraph. Specifically the Examiner states that the term "shows higher specificity for tumors of these cells" is unclear and lacks antecedent basis. Applicants respectfully traverse.

Applicants submit that it is readily apparent that "these cells" refers to the cells recited in claim 1. Applicants also submit that one skilled in the art is well aware of the meaning of "higher specificity" for one cell type over another. Nevertheless, without acquiescing in any way in the propriety of the rejection, applicants have amended claim 4 to specifically recite the cell types listed in claim 1, and specified that the second antibody exhibits enhanced binding to tumor cells over their normal counterparts. One skilled in the art readily can determine whether or not an antibody exhibits enhanced binding to, for example, a B-cell tumor versus a normal B-cell. Accordingly, withdrawal of the rejection respectfully is requested.

**Rejection under 35 USC § 102(e)**

Claims 1, 3-5, 9, 11, 12, 16, 19-22, 26, 39-41 43, and 46 are rejected under 35 USC § 102(e) over US Patent No. 5,776,456 ("the '456 patent"). Specifically, the Examiner alleges that the '456 patent teaches therapeutic methods for the treatment of B-cell disorders. Applicants respectfully traverse.

It is axiomatic that, for a prior art reference to be anticipatory, every element of the claimed invention must be identically shown in a single reference. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990). The '456 fails to describe every element of the claimed invention and, accordingly, cannot anticipate the claimed invention.

The instant claims are directed to treatment of domestic animals, for example, cats, dogs, or horses. The '456 patent fails to describe methods of treating domestic animals and, accordingly, cannot anticipate the claimed invention. Withdrawal of the rejection respectfully is requested.

### **Rejections for Obviousness-Type Double Patenting**

Claims 1-12, 14-27 and 32-48 are rejected for obviousness-type double patenting over claims 1-5, 7-22, 25, 32, and 33 of US Patent No. 6,306,393 ("the '393 patent"), in view of US Patent No. 5,837,242. Claims 1-12, 14-28, 32, 37-39 and 41-48 are rejected over claims 1-5, 7-22, 25, 32, and 33 of US Patent No. 6,306,393, in view of Rybak. Claims 1-12, 14-27, 32, 37-39 and 41-48 are rejected over claims 1, 4-13, 15-19, and 23 of US Patent No. 6,183,744. Claims 1-12, 14-27, and 32-48 are rejected over claims 1, 4-13, 15-19, and 23 of US Patent No. 6,183,744 ("the 744 patent"), in view of US Patent No. 5,837,242. Claims 1-12, 14-28, 32, 37-39 and 41-48 are rejected over claims 1-5, 7-22, 25, 32 and 33 of US Patent No 6,183,744, in view of Rybak. The rationale for each of these rejections is essentially identical and therefore applicants will address the rejections together.

The gravamen of the rejections is that the claimed methods are obvious variations over the treatment methods described in the cited patents. Applicants respectfully traverse because nothing in the cited patents teaches or suggests the instantly claimed methods of treating domestic animals.

The primary references, the '393 and '744 patents, refer to treatment of B-cell malignancies in humans and make no reference to treatment of domestic animals. Humans are not domestic animals. Accordingly, the cited references neither teach nor suggest any methods of treating domestic animals and no *prima facie* case of obviousness exists and the rejection should be withdrawn.

The instant rejections appear, in fact, to be based on an improper "obvious to try" standard. See *Novo Nordisk A/S v. Becton Dickinson & Co.*, 304 F.3d 1216, 1219-20 (Fed. Cir. 2002). Thus, even if, *arguendo*, the cited references contained some suggestion to extend the treatment methods to domestic animals, nothing in any of the references would have provided one of ordinary skill in the art with a reasonable expectation that those methods would be effective in domestic animals. The well-known differences in reactivity between human and dog cells are exemplified in Example 1 of the instant application, where a variety of known antibodies (LL2, LL1, A103, Leu 4, Leu-16 and H-Le-1) were found not to show high cross-

reactivity with dog cells. These results further demonstrate that there would have been no motivation to use the recited antibody therapy in domestic animals for the treatment of disorders of B-cells, T-cells, myeloid-cells, mast-cells, or plasma-cells. Accordingly, withdrawal of the rejection respectfully is requested.

**CONCLUSION**

In view of the above remarks and amendments, it is respectfully submitted that this application is in condition for allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to telephone the undersigned at the number listed below if the Examiner believes such would be helpful in advancing the application to issue.

If any additional fees are required for the filing of this paper, applicants authorize the Commissioner to charge any deficiency to Deposit Account No. 08-1641.

Respectfully submitted,

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By

A handwritten signature in black ink, appearing to read 'P. Booth', written over a horizontal line.

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